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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,362	05/13/2005	Margaret T Virgallito	102790-138(30074)	4732
27389 7590 05/08/2009 NORRIS, MCLAUGHLIN & MARCUS 875 THIRD AVE 18TH FLOOR NEW YORK, NY 10022				
EXAMINER				
CHAWLA, JYOTI				
ART UNIT		PAPER NUMBER		
1794				
MAIL DATE		DELIVERY MODE		
05/08/2009		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/533,362

**Applicant(s)**

VIRGALLITO ET AL.

**Examiner**

JYOTI CHAWLA

**Art Unit**

1794

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on 21 January 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 2 and 4-11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-2, 4-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/CDC)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_
- Paper No(s)/Mail Date \_\_\_\_\_

**DETAILED ACTION**

Applicant's submission filed on 1/21/2009 has been entered as compliant. Claim 3 has been cancelled, claims 1, 7 and 11 have been amended. Claims 1-2, 4-11 are pending and examined in the current application.

***Claim Rejections - 35 USC § 112***

Rejection of claim 7 under 35 U.S.C. 112, second paragraph, for being indefinite for the recitation of "gelatin and or pectin" has been withdrawn based on applicant's amendment dated 1/21/09.

***Claim Rejections - 35 USC § 102***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

(1) Claims 1-2,4-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Chen et al (WO 00/42992, IDS reference), hereinafter Chen.

References and rejections are incorporated herein and as cited in the office action mailed 8/20/2008.

Applicant has amended claim 1 and added the amount of food acid , which is the same limitation as was recited in previously rejected claim 3 (now cancelled claim 3), into claim 1.

Regarding the amended claim 1, Chen teaches an edible film composition for delivering an active agent to the oral cavity, the composition comprising a water-dispersible film-forming material selected from a cellulose ether and a starch, and a food acid (Page 3, lines 30 to page 4, line 6, Page 5, lines 8-12, Page 11, lines 17-26, Page 14, line 15 to

page 15, line 3). Regarding the amount of food acid being at least about 8 wt %. Chen teaches of applicant's recited acids as part of buffering agents as well as stabilizers (Page 11, lines 17-26). Regarding the concentration of acids, Chen teaches that the buffering agents can be 0.1-10% and stabilizing agents can be 0.01 to 5%, i.e., the total acidic component as taught by Chen can be 15% of the film composition (Page 15, line 12). Thus, Chen teaches of acid in the range recited by the applicant of at least about 8 wt % based on the weight of the composition.

Rejections of claims 2, 4-7 are maintained for reasons of record.

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

(A) Claims 8-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen (WO 00/42992) in view of Dictionary.com Unabridged (v 1.1), definition of term wafer.

Chen has been relied upon to reject claims 1-2,4-7 under 35 USC 102(b) as discussed above and in the previous office action.

References and rejections are incorporated herein and as cited in the office action mailed 8/20/2008.

Applicant's amendments to claim 11, changing "Packaging" to recite "A packaging" does not provide patentable distinction to the claim and the rejections made in the previous office action are maintained for reasons of record.

***Response to Arguments***

Applicant's arguments filed 1/21/2009 have been fully considered but they are not persuasive.

On page 4-12 of applicant alleges that "Nowhere did Chen realize or even hint at problems when formulating high acid content formulations" (see page 9, lines 6-7). Whereas applicant has pointed out Chen's edible film composition may have food acid amount in the claimed range for a different purpose, applicant has not presented arguments against the fact that Chen teaches that buffering agents can be 0.1 -10% and stabilizing agents can be 0.01 to 5%, that both buffering agents and stabilizing agents can be foods acids, i.e. the total acidic component as taught by Chen can be 15% of the film composition (see Chen, page 15, lines 12; also see rejection of claim 3). Thus, irrespective of applicant's allegation that "the technical function of these materials are taught only in the present application" (see page 9, lines 3-4), Chen anticipates the claimed invention of claim 1. It is noted that a recitation of the intended use (i.e. above said "technical functions" of materials) of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Further, whereas applicant's observation that the example compositions provided by Chen do not have food acid in the claimed range (see pages 9-11 of applicant's response) is correct, it does not imply that Chen does not teach the above limitation as examples may not cover all the teachings of the reference.

**Conclusion**

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JYOTI CHAWLA whose telephone number is (571)272-8212. The examiner can normally be reached on 9:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks can be reached on (571) 272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JC/  
Examiner  
Art Unit 1794

/KEITH D. HENDRICKS/

Supervisory Patent Examiner, Art Unit 1794